

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

LARRY W. FAIRCLOTH,
186 Diamante Drive
Inwood, WV, 25428
1:16-cv-373

Case No. 2:16-5267

Plaintiff,

vs.

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD, 20993

ROBERT CALIFF, M.D.,
Commissioner of Food and Drugs,
10903 New Hampshire Avenue
Silver Spring, MD, 20993

and

SYLVIA MATTHEWS BURWELL
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Defendants.

PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS

NOW COMES Plaintiff, by and through his attorneys, The Lane Law Firm, and hereby responds to Defendants' Motion to Dismiss. For the reasons stated below, Plaintiff respectfully requests that this Court **DENY** Defendants' Motion to Dismiss.

INTRODUCTION

Plaintiff filed this suit against the Food and Drug Administration (“FDA”), a United States regulatory agency, Robert Califf, the commissioner of said agency, and Sylvia Matthews Burwell, the Secretary of Health and Human Services, (collectively referred to as “Defendants”) for their actions in deeming e cigarettes, e liquid, and related products to be subject to the Tobacco Control Act, and regulating such products accordingly. As Plaintiff has explained in his complaint, the Tobacco Control Act is an act that specifically regulates tobacco products and tobacco derivatives. (Compl.¶ 15). It is devoid of any language that a reasonable reader of the statute could find to apply to vaping or e liquid products. In fact, many of the vaping devices, and much of the e liquid, on the market are completely tobacco and nicotine free. (Compl.¶ 7). Despite these facts, and despite the fact that the Tobacco Control Act is, on its face, limited to the regulation of tobacco products and their harmful effects, Defendants have deemed vaping and e liquid products to be subject to the statute and have begun regulating them in the same way. (Compl.¶ 26).

As laid out in detail in the Complaint, Defendants’ regulations of e liquid and vaping products violate the Administrative Procedures Act in that they reach well beyond Defendants’ mandate and directly burden Plaintiff by raising the cost, and limiting the availability, of e liquid and vaping products. (Compl. ¶¶ 36-52). Furthermore, Defendants’ actions are also constitutional violations in that they burden free expression by limiting access to, and knowledge of, vaping products, and in that they represent a usurpation of state authority in violation of the tenth amendment. (Compl.¶¶ 53-60). Defendants have not attacked these claims in their motion to dismiss. Rather, Defendants have chosen to seek dismissal of Plaintiff’s complaint on jurisdictional grounds. (Mot. to Dis., p. 8). Plaintiff’s complaint sufficiently demonstrates

Plaintiff's standing and the ripeness of his claims for review. He further supports his standing and the ripeness of his claims in the arguments he makes below.

STANDARD OF REVIEW

"A district court should dismiss a complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) if the complaint fails to allege facts upon which subject matter jurisdiction can be based or if the jurisdictional allegations in the complaint are not true." *McLaughlin v. Safeway Servs., LLC*, 429 F. App'x 347, 348 (4th Cir. 2011). "The district court should grant such a motion only if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Misel v. Mazda Motor of Am., Inc.*, 420 F. App'x 272, 273 (4th Cir. 2011)(Internal Quotations Omitted). For purposes of a review under Rule 12(b)(1), "all the facts alleged in the complaint are assumed to be true and the plaintiff, in effect, is afforded the same procedural protection as he would receive under a Rule 12(b)(6) consideration." *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982).

ARGUMENT

I. Plaintiff has standing to bring his claims.

As Defendants have explained in their motion to dismiss, a plaintiff has article three standing if it can establish an (1) injury in fact, (2) causation, and (3) redressability. (Mot. to Dis., p. 8); see also *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 582 (1992). Defendants, in their motion to dismiss, do not address the redressability prong, but claim Plaintiff failed to allege an injury in fact or establish that Defendants caused his injuries. The following two sections address each point in turn.

A. Plaintiff has suffered an injury in fact.

Plaintiff faces actual imminent harm from Defendants' regulation of vaping products and e liquid. Defendant claims that Plaintiff has not alleged actual imminent harm, arguing the

harm Plaintiff complains of is future harm. (Mot. to Dis., p. 11). Plaintiff filed his complaint on June 10th of this year and explains that the deeming rule and the attendant regulations of vaping products and e liquid go into effect on August 8th. (Compl.¶¶ 53-60). Thus, although the harms that would inevitably come to bear upon Plaintiff were a few months away at the time the complaint was filed, they have now taken effect and can no longer be considered remote.

Even if the regulations were still yet to be implemented, the fact that harm will occur in the future is not a barrier to standing as Defendants contend. The Fourth Circuit has made clear that “[p]laintiffs have standing to sue to prevent anticipated future conduct if they demonstrate a realistic danger of sustaining a direct injury as a result.” *Richmond Tenants Org., Inc. v. Kemp*, 956 F.2d 1300, 1305 (4th Cir. 1992). Following the same line of reasoning, this court has stated that “[f]uture injury may confer standing.” *EQT Prod. Co. v. Wender*, No. CV 16-00290, 2016 WL 3248503, at *4 (S.D.W. Va. June 10, 2016)(citing *Defs. of Wildlife*, 504 U.S. at 560). Expounding on this concept, this court explained that “a plaintiff need not prove that he is guaranteed to suffer future injury, he must at least be able to show a sufficient likelihood of encountering later harm.” *Id.* (Internal Quotations Omitted); see also *Bocook v. Ashland Oil, Inc.*, 819 F. Supp. 530, 536 (S.D.W. Va. 1993)(Granting damages to a plaintiff that had yet to suffer actual injuries for “enhanced risk” and “anticipated harm” resulting from toxic pollution the plaintiff was wrongly subjected to).

Plaintiff has certainly alleged a sufficient likelihood of encountering later harm. Plaintiff has explained that Defendants’ unconstitutional and arbitrary actions will subject vaping products and e liquid to a complete regulatory scheme involving everything from premarket approval by Defendants to testing and labeling of products. (Compl.¶¶ 26-35). These new requirements will prove costly for the young vaping industry. Plaintiff, like many other vaping

products and e liquid consumers throughout the country, will bear the burdens of much of these costs, not only in direct sales prices, but in health care. (Compl.¶¶ 30-33). The increase in prices and decrease in availability of vaping products, which is inevitable to result from these regulations, will force many consumers who, like Plaintiff, are recovering tobacco addicts using vaping products as a safer alternative, to go back to using tobacco. (Compl.¶¶ 30-33). As explained in the complaint, this is certain to cost Plaintiff hundreds of thousands of dollars in health care costs. (Compl.¶¶ 30-33).

B. Defendant caused Plaintiff's Injuries

Defendants further claim they did not cause Plaintiff's injuries because he is a consumer and not a manufacturer of vaping products and e liquids. (Mot. to Dis., p. 8). Courts have consistently found standing where a defendant's actions have caused increased prices and decreased availability in the market. *See Laumann v. Nat'l Hockey League*, 907 F. Supp. 2d 465, 490 (S.D.N.Y. 2012) (Defendants actions "resulting in decreased consumer choice and increased price . . . [amount to] an allegation that states an injury"); *Taylor v. Volkswagen of Am., Inc.*, No. C07-1849RSL, 2008 WL 618618, at *3 (W.D. Wash. Mar. 3, 2008) (Finding Plaintiff had standing where he "alleg[ed] that he was injured as a result of . . . [the defendant's] policy and practice, which increased prices for consumers"). Defendants are clearly the cause of the imminent increase in costs and decrease in availability Plaintiff alleges in his complaint. (Compl.¶ 27). The vaping industry has, heretofore, operated with little government interference or regulatory costs. (Compl.¶ 27). This new slew of federal regulations, which will subject the entire industry to this country's behemoth tobacco regulation scheme overnight, will make prices go up for all market participants and will cause some vaping and e liquid products providers to go out of business. Many will be unable to provide their products in rural areas, like the area Plaintiff lives in, and will be restricted to bigger cities. This will mean Plaintiff, and many

consumers like him, will face increased costs in vaping products, increased dependency on tobacco products, and the increased health care costs associated with that.

Defendants have argued that Plaintiff is at fault for the inevitable harm to his health posed by the regulations because he is choosing to consume these products. (Mot. to Dis., p. 13). The idea that addiction is the choice of the addict is outdated and has no place in this court system. Indeed, the most cutting edge research shows that addiction is a disease from which the addict suffers, as opposed to a moral failing and a choice. Therefore, if anything, the government should be aiding Plaintiff in his ailment, instead of exacerbating it. At any rate, whether Plaintiff is an addict, and whether that addiction is a choice, are factual questions not appropriate at the dispositive motion stage. *See Bordonaro v. Johnston Cty. Bd. of Educ.*, 938 F. Supp. 2d 573, 579 (E.D.N.C. 2013) (“a question of fact . . . is not appropriately dismissed at [the motion to dismiss] stage so long as plaintiff has pleaded sufficiently to state her claim.”) Accordingly, Plaintiff has adequately plead that he has standing to bring his claims.

II. Plaintiff's claims are ripe for review.

Ripeness is an Article III justiciability doctrine similar to standing. *See Scoggins v. Lee's Crossing Homeowners Ass'n*, 718 F.3d 262, 270 (4th Cir. 2013). Under the ripeness doctrine, “[a] case is fit for adjudication when the action in controversy is final and not dependent on future uncertainties.” *Id.* In support of their ripeness argument, Defendants essentially make no arguments that were not already made in their estanding argument. (Mot. to Dis., p. 17). Contrary to Defendants' contentions, Plaintiff's harms are no longer uncertain as the regulations Plaintiff complain of took effect in August of this year. Furthermore, as Plaintiff has explained above, the substantial burden Plaintiff is bound to bear as a result of these regulations are far from uncertain. Rather, they are the inevitable results of Defendants' arbitrary and unconstitutional overreaching.

CONCLUSION

WHEREFORE, based on the foregoing, Plaintiff respectfully requests that the Court
DENY Defendants' Motion to Dismiss.

Respectfully Submitted,
By Larry Faircloth
Through Counsel



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